ORD Support of Toxics Substances Control Act Implementation

U.S. EPA Office of Research and Development

Briefing for Dr. Richard Yamada
June 22, 2017

TSCA Background*

- **Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed and went into effect on June 22, 2016:**
  - **Celebrate one year anniversary!!**
- **Act amends and updates the Toxic Substances Control Act of 1976 (TSCA).**
- **Large bipartisan support shown in both House and Senate.**
- **New TSCA received broad stakeholder support.**
- **2016 amendment represented the first major update to an environmental statute in about 20 years.**

* TSCA Background information liberally borrowed from prior presentations prepared by OCSPP.

TSCA Background – Sections of TSCA

- Section 4 – Testing of chemicals
- Section 5 – Manufacturing and Processing Notices
  - "New Chemicals"
  - Pre-manufacture Notices "PMNs"
- Section 6 – Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures
  - "Existing Chemicals"
  - Major impact of "New TSCA"
- Section 8 – Reporting and Retention of Information
  - The TSCA Inventory
  - Chemical Data Reporting "CDR"

TSCA Background – Major Changes

- **Existing chemicals:**
  - New TSCA: **Mandatory to evaluate risks from existing chemicals with clear and enforceable deadlines.**
  - Old TSCA: **62,000 chemicals "grandfathered" in; no duty to review; no deadlines for action.**
  - New TSCA: **Chemicals assessed using a risk-based safety standard with costs and other non-risk factors excluded.**
  - Old TSCA: **Chemicals assessed against a risk-benefit balancing standard.**
  - New TSCA: **Unreasonable risks identified in the risk evaluation must be eliminated (Risk management).**
  - Old TSCA: **Significant risks might not be addressed due to cost-benefit balancing and no mandate to act.**

Old TSCA

TSCA Background – Major Changes

- **Development of health and safety information:**
  - **New TSCA: Expanded authority for EPA to require development of chemical information whenever needed (prioritization, risk evaluation, etc.).**
  - **Old TSCA: Required lengthy rulemaking process. EPA had to prove a chemical presents an unreasonable risk.**

- **EPA Funding:**
  - **New TSCA: Up to $25 M total in annual user fees can supplement Congressional appropriations**
  - **Old TSCA: Cap on individual use fees at $2.5 K and limited fee collection authority**

TSCA Background – Major Changes

- **Review of New Chemicals:**
  - **New TSCA: Requires EPA to make an affirmative determination on new chemicals before entry into the marketplace.**
  - **Old TSCA: New chemicals could enter the market in the absence of EPA action.**

- **Confidential Business Information:**
  - **New TSCA: Requires substantiation of certain CBI claims, ensuring that those claims are merited.**
  - **Old TSCA: No statutory substantiation requirements for CBA claims.**

TSCA Background – State-Federal Partnership

- **TSCA does not prevent states from acting on chemical risks that EPA has not acted on.**

- **IF EPA does act, the following State actions are preserved:**
  - **Actions taken before April 2016**
  - **Implementation of other environmental laws (air, water, waste treatment, disposal, reporting, monitoring, etc.)**
  - **Co-enforcement of identical requirements and penalties that do not exceed the federal maximum**
  - **Actions on chemicals identified as low-priority by EPA.**

Focus of ORD Activities Supporting OPPT for TSCA Implementation

- Chemical prioritization
- Alternative toxicity strategies document
- Chemical evaluation
- Systematic Review
- Regulatory review

Chemical Prioritization

- TSCA requires that EPA establish a risk-based process to identify "high" and "low" priority substances.
- A high priority chemical is one that may present an unreasonable risk of injury to health or the environment.
- TSCA requires EPA develop a procedural rule to establish a process for prioritizing chemicals (June 2017).
- TSCA outlined factors that need to be considered during prioritization:
  - Chemical hazard (toxicity)
  - Exposure potential
  - Persistence and bioaccumulation
  - Potentially exposed or susceptible subpopulations
  - Storage near significant sources of drinking water
  - Conditions of use and volume.

Chemical Prioritization – ORD Response

- ORD formed a team to assist OPPT with prioritization and has been meeting with OPPT staff.
- ORD developed and delivered a data matrix to identify available information for the TSCA 2014 chemical list (91+ chemicals). The list contains information for most of the factors the need to be considered:
  - Data matrix being expanded to the TSCA 2012 list of 345 chemicals.
- Working with OPPT, ORD is identifying information to characterize potentially exposed or susceptible subpopulations.
- Exploring options for developing metrics for chemical storage adjacent to drinking water supplies (with OW-OGWDW).

Chemical Prioritization – Informed by ORD Research, Data and Information

- Former and current investments result in ORD being able to provide data and information that informs TSCA activities.
- Physical chemical properties informed by OPERA database and QSAR models – includes information on persistence and bioaccumulation.
- Toxicological properties informed by ORD's Chemical Dashboard, EcoTox Database, GenRA, and RapidTox.
- Exposure properties informed by ORD's ExpoCast, and SHEDS-HT.
- Active efforts underway to expand breadth and depth of information for TSCA chemicals.

Alternative Toxicity Testing Strategies

- TSCA requires completion of a strategic plan for promoting the development and implementation of alternative (non-animal) testing methodologies and protocols:
  - Strategy document due June 2018.
- Development and application of non-animal testing approaches supported by multiple U.S. Agencies and internationally.
- EPA actively participates in ICCVAM – the Interagency Coordinating Committee on the Validation of Alternative Methods:
  - Permanent committee of NIEHS
  - OCSPP represents EPA on committee

Alternative Toxicity Testing Strategies – ORD Response

- ORD formed a team to assist OPPT with the development of the alternatives strategy document:
  - Team includes toxicologists and exposure scientists.
- ORD staff actively participate in both interagency and interagency activities.
- Team has met with OPPT to discuss scope, approach, and schedule for development of strategy document.
- OPPT and ORD teams discussed options for the outline of the strategy document:
  - OPPT to publish outline in FRN this summer.
- Writing teams will engage this summer with goal of completing draft strategy document by end of calendar year.

Chemical Risk Evaluations

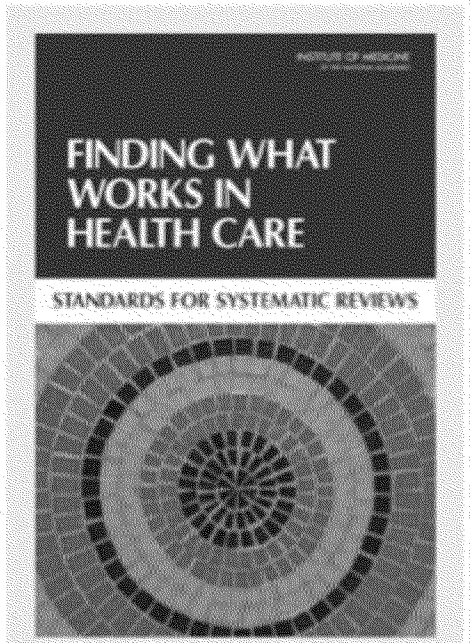
- **Health and Environmental Research Online "HERO" database to house, review and integrate literature = transparency**
- **Scoping & Problem Formulation for assessment excellence**
- **Discipline expertise**
  - **Epidemiology**
  - **Mode of action**
  - **Cancer Assessment**
  - **Developmental Toxicity**
  - **etc**
- **IRIS assessment value**
  - **Subject matter expertise**
  - **Existing literature reviews**
- **Systematic Review Support**
  - **Human Health, Exposure, Ecotoxicity**

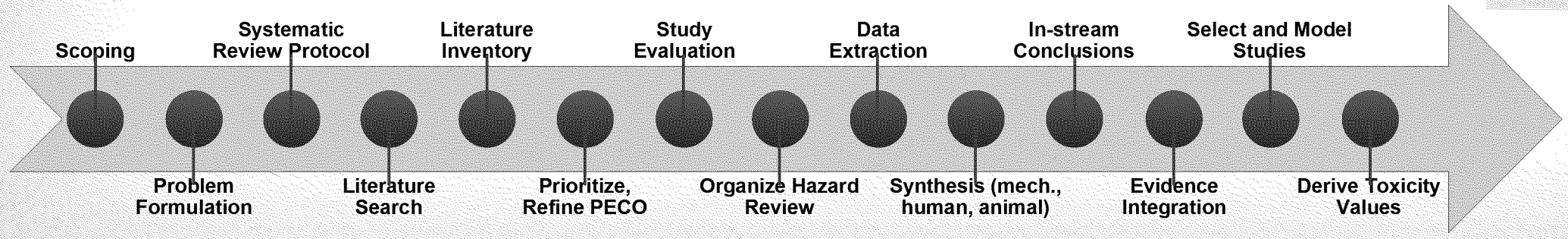
Chemical	NCEA support
Asbestos	**OPPT workgroup participation**
Cyclic aliphatic bromide (HBCD)	**Human health assessment complete**
1,4-dioxane	Example for systematic review; existing IRIS assessment
Carbon tetrachloride	Existing IRIS assessment
Trichloroethylene (TCE)	Existing IRIS assessment
Perchloroethylene (Perc)	Existing IRIS assessment
Methylene chloride	Existing IRIS assessment
1-bromopropane	Toxicity discipline support
Pigment Violet 29	Toxicity discipline support
N-methyl pyrrolidone	Toxicity discipline support

Systematic Review Guidance

- **Systematic Review is a critical foundation for TSCA Risk Evaluations**
  - Structured and documented process for transparent literature review
  - This knowledge base has already proven critical to meeting TSCA statutory deadlines and supporting OPPT staff as they navigate what risk evaluation will be under new TSCA.

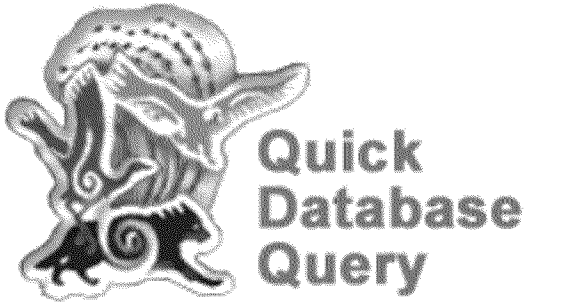
… systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies.





Systematic Review Guidance

- **ORD provides five elements of support in Systematic Review**
  1. Health and Environmental Research Online “HERO” (NCEA)
  2. ECOTOX knowledgebase of curated data from published ecotoxicology literature (NHEERL)
  3. Training from international experts and support from NCEA systematic review experience
  4. Practical experience and visionary innovation to provide speed and efficiency “phone a friend” support
  5. Agency wide Community of Practice in Systematic Review co-led by ORD NCEA and OCSPP OSCP – will connect and coordinate systematic review across EPA and provide key support to OPPT risk evaluations.



Regulatory Review

- ORD participates in the regulatory review of rule making associated with the implementation of TSCA
  - TSCA Risk Evaluation Rule Review
  - TSCA Chemical Prioritization Rule Review
  - PBT Chemical Rulemaking (in development)
- Regulatory review activities coordinated by ORD Office of Science Policy